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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/837,620

Applicant(s)

CHEN ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-28 are included in the prosecution of this application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 3 recites, "wherein the moisture content is expressed as dew point, frost point or relative humidity." It is unclear to the examiner what exactly the limitation of the claim is with out any numbers or temperatures.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1-3, 5-10, 13-19, 22-23, and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5985309).**

Edwards et al disclose preparation of particles for inhalation. Edwards discloses the method of spray drying insulin, which is combined with lactose and DPCC, was and ethanol. The solution is spray dried with an inlet temperature of 110 degrees Celsius

Art Unit: 1616

and an outlet temperature of 61 degrees Celsius. The tap density is .05 and the aerodynamic diameter is 1.5 microns. (Note examples, especially 9).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 1-6, 10-14, 16-20, and 22-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Bennett et al (WO 01/00312).**

WO discloses a spray drying process for producing dry powder formulations for pulmonary delivery (pg. 3). The atomized formulation of liquid is introduced into the conditioning zone where the residence time, temperature, and relative humidity are controlled to allow the particles to reach equilibrium (pg. 4). The formulation is then transferred to a dryer where a heated gas is introduced where the relative humidity is significantly lower than the conditioning zone (pg. 17) and the dry particles are collected in a cyclone collector (pg. 5 and example 2). The aqueous feed stock formulation is dried with an inlet temperature of 200-215 degrees Celsius and an outlet temperature of 52-72 degrees Celsius (example 2). WO discloses the relative humidity of the drying zone in Table 1, 2, 4). Further, the aerodynamic diameter is taught to be between 1-5 microns (pg. 18). The reference teaches that controlling all these conditions allow for stable particles (pg 22).

\*It is to the examiner's understanding that the relative humidity corresponds to the dew point range given in claim 4.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1616

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 2 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5985309) or Bennett et al (WO 01/00312) in view of Broadhead et al (Drug Development and Industrial Pharmacy, Vol. 18, 1992).**

As set forth above, Edwards and Bennett disclose spray-dried particles.

Edwards does not teach the method of collecting the particles or using nitrogen

Bennett does not teach nitrogen as the drying gas.

Broadhead et al teaches the state of the art of spray drying particles for inhalation. The reference teaches the use of a cyclone separator, an open cycle dryer, that collects the particles after drying. Closed dryer systems also exist in which an inert gas like nitrogen can be used. Closed dryers enable the use of organic mediums as the feed medium. (pg. 1171).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use nitrogen as the drying gas in Edwards et al's or Bennett et al's method, if the composition required an organic feed medium.

**Claims 10-14, 16-20, and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable Bennett et al (WO 01/00312).**

WO discloses a spray drying process for producing dry powder formulations for pulmonary delivery (pg. 3). The atomized formulation of liquid is introduced into the conditioning zone where the residence time, temperature, and relative humidity are controlled to allow the particles to reach equilibrium (pg. 4). The formulation is then

transferred to a dryer where a heated gas is introduced where the relative humidity is significantly lower than the conditioning zone (pg. 17) and the dry particles are collected in a cyclone collector (pg. 5 and example 2). The aqueous feed stock formulation is dried with an inlet temperature of 200-215 degrees Celsius and an outlet temperature of 52-72 degrees Celsius (example 2). WO discloses the relative humidity of the drying zone in Table 1, 2, 4). Further, the aerodynamic diameter is taught to be between 1-5 microns (pg. 18). The reference teaches that controlling all these conditions allow for stable particles (pg 22).

Assuming the relative humidity does not correspond to the dew point, it is deemed obvious to one of ordinary skill in the art to manipulate the conditions since Bennett teaches the general guidance and importance of reducing the final moisture content of the particles by controlling the temperature and humidity of the process. One would be motivated to do depending on the feed stock formulation and its requirements as taught by Bennett.

**Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5985309) in combination with Bennett et al (WO 01/00312).**

Edwards et al disclose preparation of particles for inhalation. Edwards discloses the method of spray drying insulin, which is combined with lactose and DPCC, was and ethanol. The solution is spray dried with an inlet temperature of 110 degrees Celsius and an outlet temperature of 61 degrees Celsius. The tap density is .05 and the aerodynamic diameter is 1.5 microns. (Note examples, especially 9).

Edwards et al does not teach the collection step of the spray-dried particles.

WO discloses a spray drying process for producing dry powder formulations for pulmonary delivery (pg. 3). The atomized formulation of liquid is introduced into the conditioning zone where the residence time, temperature, and relative humidity is controlled to allow the particles to reach equilibrium (pg. 4). The formulation is then transferred to a dryer where a heated gas is introduced where the relative humidity is significantly lower than the conditioning zone (pg. 17) and the dry particles are collected in a cyclone collector (pg. 5 and example 2). The aqueous feed stock formulation is dried with an inlet temperature of 200-215 degrees Celsius and an outlet temperature of 52-72 degrees Celsius (example 2). WO discloses the relative humidity of the drying zone in Table 1, 2, 4). Further, the aerodynamic diameter is taught to be between 1-5 microns (pg. 18). The reference teaches that controlling all these conditions allow for stable particles (pg 22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Edwards et al and Bennett et al since both teach a method of spray drying inhalation particles. One would be motivated to do so since Bennett et al teach a method of collecting the particles.

### ***Conclusion***

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.


If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG



7/26/02



MICHAEL G. HARTLEY  
PRIMARY EXAMINER